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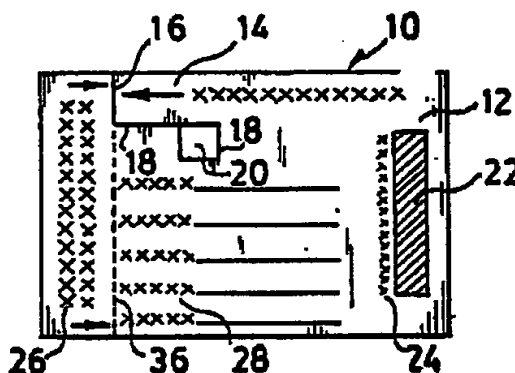
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US91/07249 (22) International Filing Date: 10 October 1991 (10.10.91) (30) Priority data: 598,946 17 October 1990 (17.10.90) US (71) Applicant: SPS MEDICAL SUPPLY CORPORATION [US/US]; 1250 Scottsville Road, Rochester, NY 14624 (US). (72) Inventor: SCOVILLE, John, Robert ; 28 Mertensia Lane, Henrietta, NY 14467 (US). (74) Agents: MARJAMA, Owen, D. et al.; Marjama & Pincelli, 488 White Spruce Blvd., Rochester, NY 14623 (US).			(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), LU (European patent), NL (European patent), SE (European patent).  Published With international search report.

(54) Title: DISPOSABLE TAMPER EVIDENT LOCKING DEVICE



(57) Abstract

A locking device (10) in the shape of a unitary body (12) formed from a bio-degradable material which includes an element (14) with at least one free end formed integral with said body (12). The severable element (14) is designed to engage and secure a container lock mechanism (42, 44, 46, 48) when the container (50, 54) is in a closed position, whereby the free end (16) of the element (14) is capable of being mechanically or adhesively secured to said unitary body to form a seal, with said device being designed to fracture upon opening of the container lock mechanism (42, 44, 46, 48) thereby providing visible evidence of the lock mechanism (42, 44, 46, 48) being opened.

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DISPOSABLE TAMPER EVIDENT LOCKING DEVICEBACKGROUND OF THE INVENTIONField of the Invention:

The present invention relates in general to locking mechanisms for containers for sterilization and storing articles, and more particularly to a disposable tamper evident security device for providing an indication of whether the container has been opened subsequent to sterilization.

Description of the Prior Art:

Sterilization container systems have been developed to facilitate the storage of sterilized articles in a manner such that their sterilized state is maintained during storage. These container systems permit entry of the sterilizing medium into the container during the performance of the sterilization process, but prevent the entry of contaminating organisms into the containers.

Sterilization containers which contain articles which have been sterilized are commonly left unattended for relatively long periods of time before the articles are used. During this storage period the possibility exists that the container will be opened, causing contamination of the articles, and then

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subsequently reclosed. Such an event is not readily visible. Most medical instrument sterilization containers employ some form of security device to give evidence of sterile integrity prior to use. Closures for sterilization containers are often provided with seals which must be destroyed to enable opening of the locking mechanism for the container. It is also known to use so-called indicator adhesive tapes as seals, i.e. tapes which change their color during sterilization. The locking mechanism of such sterilizing containers can only be opened by destroying such an indicator tape.

U.S. Patent 4,820,499 describes a device and a means for securing a paper data card which also indicates by a punched hole that the sterilizing container has been opened. Devices described in U.S. Patents 4,562,047 and 4,915,913 are fabricated of plastic and designed to be fractured when the container is opened and provide a permanent indication of the incident. These devices are also provided with means for indicating that the container has been exposed to a sterilization process.

All known "tamper evident" devices require additional elements to: (1) automatically indicate whether the container has been sterilized and (2) indicia fields for inscribing data. Many of the current "tamper evident" devices are fabricated of high temperature resistant injection moldable plastic resins. These resins are expensive and consume non-renewable resources (oil), are non-biodegradable and when incinerated, burn with high temperatures and emit toxic gases which are known to pollute the atmosphere.

An object of the present invention is to provide a "tamper evident" device which integrates the various discrete elements, i.e. locking function, sterilization indicator and data elements into a single disposable device.

Another object of the present invention is to provide a tamper evident locking device that reduces the impact on the waste disposal systems in health care facilities and land fills, while reducing or eliminating the production of toxic by-products resulting from incineration.

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A further objective of the present invention is to provide an inexpensive disposable "tamper evident" locking device having simple, yet functionally effective design features.

#### SUMMARY OF THE INVENTION

The present invention is directed to a tamper evident seal or locking device for a sterilization container, and in one embodiment, comprises of a body formed of heavy paper or paperboard tag stock, a severable element with a free end which has been formed by appropriate die-cuts from said body, a field or area to which sterilization indicator material is applied, a second field or area printed with instruction for use indicia, a third field or area to which a permanent type pressure sensitive adhesive with release liner is applied, an area which has been die-cut and removed prior to use, and a crease to aid in folding the adhesive area to seal or lock the device.

In operation, the free end of the severable element is inserted into the bore or keyway of a closed latch mechanism of a sterilization container in such a way that the free end emerges from the open end and is free for attachment or locking. The pressure sensitive adhesive is "activated" by stripping away a protective release liner and the area containing the adhesive is folded along the crease to adhere to the free end of the severable element thereby completing the seal or locking action of the device. Upon opening the latch mechanism, the severable element is fractured, automatically indicating that the container has been previously opened.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a plan view of the face side of one embodiment of a device of the present invention;

Figure 2 is a view of the back side of the device of Figure 1;

Figure 3 is a side or edge view of the device of Figure 1;

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Figure 4 is a view of the device of Figure 3 with the device in the closed or locked position;

Figure 5 is a plan view of the face side of a second embodiment of a device of the present invention.

Figure 6A is a plan view of the backside an alternative embodiment of a device of the present invention;

Figure 6B is a view of the front side of the device of Figure 6a;

Figure 6C is a perspective view showing the device of Figures 6A and 6B in the closed or locked position;

Figure 6D is a view of the device of Figure 6C, in the severed or fractured condition;

Figure 7 is a perspective view of a sterilization container illustrating a lock mechanism utilizing the device of the present invention;

Figure 8 is an enlarged view from Figure 7 showing the latch mechanism in the closed position with the device of the present invention in the closed or locked position.

Figure 9 is a view of the Figure 8 with the latch mechanism in the open position.

#### DETAILED DESCRIPTION OF THE INVENTION

The locking device of the present invention, in its simplest embodiment, is in the shape of a unitary body formed from a biodegradable and renewable material, and includes a severable element with at least one free end formed integral with said unitary body. The severable element of the device is designed to engage a container lock mechanism and when in a locked or closed position the free end is mechanically or adhesively secured to said unitary body to form a seal, thus preventing its removal or opening of said lock mechanism without providing visible evidence of tampering.

Figure 1 is a plan view of the face side of one embodiment of a tamper evident device 10 of the present invention. The device



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10 has a body 12, a severable element 14 having a free end 16 which is formed by appropriate die-cuts 18, which also results in the formation of an opening or hole 20. Opening or hole 20 serves as a means of locating the device such that it prevents movement laterally when the device is in the locked or closed position. The device further contains a first field or area 22 to which is applied a sterilization indicator material, a second field 24 to which is printed sterilization indicator interpretation instructions, a third field 26 to which is printed instructions for use, a fourth field 28 to receive variable data, and a fifth field 30 located on the back or side opposite the face side (Figure 2) to which is applied a permanent type pressure sensitive adhesive 32 (Figure 3) an appropriate protective release liner 34, and a crease 36 to aid in folding the adhesive field 30 when locking or closing the device. Figure 4 illustrates a side view of the device of Figure 1 where the release liner 34 has been stripped away and the end section containing the adhesive folded along crease 36 to seal or lock the device.

Figure 7 illustrates a perspective view of a simplified version of a sterilization container 40 which incorporates a hasp type latching element 42 in a closed position such that a "D" shaped element 46 passes through the opening 48 in the hasp. Container 40 has a hinged cover 50 with the latching element 42 pivotably attached at 52 to the front 54 of the container. To lock the container, the free end of device 10 of Figure 1 is inserted into the opening or keyway 44 in "D" shaped element 46. Figure 8 is an enlarged view of area 8-8 of Figure 7 and shows sterilization container 40 having hinged hasp type latching element 42 in the closed position. The free end 16 of severable element 14 is passed into and through opening or keyway 44 in "D" shaped element 46 in such a way that the free end emerges from the open end and "D" shaped element 46 becomes trapped in opening or hole 20 which serves as a means of locating the device and preventing lateral movement. Constraint of movement of device 10

is desirable to prevent slippage of the severable element 14 through latching element 42, and to prevent interference with other container elements such as movable handles. The protective adhesive release liner 34 has been removed exposing the pressure sensitive adhesive 32. The area to which the pressure sensitive adhesive is applied then is folded along crease 36 and adhered to the free end 16 of the severable element 14 and body 12 thereby completing the seal or locking action.

Although the device of the present invention has been illustrated as fracturing or breaking through a location described as a severable element, it should be understood that the device can be designed to fracture at any location predetermined or random. In this embodiment, upon opening the latch mechanism, the element with one free end that has been sealed or locked becomes fractured at any desired location which may be defined by perforations or along a predetermined fault line, automatically indicating that the container has been previously opened.

Figure 9 is an enlarged schematic illustration of the operation of a container latch mechanism of Figure 8 showing the tamper evident device being severed as the "D" shaped element passes through the opening 48 in hinged hasp latch 42 as it travels to the open position. This movement of the hasp latch element 42 causes a shearing action with the "D" shaped element 46 thus fracturing or breaking severable element 14.

A second embodiment of the present invention is illustrated in Figure 5, which is a plan view of the tamper evident device 60 which is substantially the equivalent of device 10 of Figure 1. Device 60 has a body 62, a severable element 64 with one free end 66 which is formed by appropriate die-cuts 68 which also results in the formation of an opening or slot 70. Slot 70 serves as a means of locating the device and preventing lateral movement. Constraint of movement of the device is desirable to prevent slippage of the severable element 64 through the latching element 42 and to prevent interference with other container elements such

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as moveable handles. The device further contains a first field 72 to which is applied a sterilization indicator material, a second field 74 to which is printed sterilization indicator interpretation instruction indicia, a third field 76 to which is printed instructions for use, a fourth field 78 to receive variable data, and a fifth field 80 on the face side, to which is applied a permanent type pressure sensitive adhesive 82 and appropriate protective release liner 84, and a crease 86 to aid in folding. In this embodiment, the adhesive layer is contained on the same side as the various fields.

Figures 6A and 6B illustrate plan views of the back and front, respectively, of an alternative embodiment of the present invention. In this embodiment, device 90 contains a severable element which comprises an elongated strip section 92 having a free end 94 and an opposite end section 96 which contains the indicia 98 and indicator material 100.

In operation the free end 94 of the severable element 92 of device 90 passes into and through the bore or opening of a keyway not unlike element 46 shown in Figure 8. The protective release liner 102 is removed exposing the pressure sensitive adhesive area 104 on the back face of the said free end 94; the free end is passed around a protruding segment of said keyway and the adhesive side of the free end is secured to itself forming a loop as shown in Figure 6C. Figure 6D is a schematic illustration of the operation of a container latch mechanism of 6C showing the tamper evident device being severed as the latch mechanism 42 travels to the open position. The movement of the latch mechanism severs the severable element 92.

It should be understood that geometric configurations other than those illustrated by the drawings may also be used in making a device of the present invention. For example:

1. A device where an elongated severable element with one free end formed from a unitary body, said elongated severable element having a shaped end to engage a slot in said unitary body and become trapped. An alternative mechanical means for

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fastening could include the form of an embossed or raised surface designed to frictionally engage a hole or opening.

2. A device where an elongated severable element with one free end formed from a unitary body, said elongated severable element having a pressure sensitive adhesive area on the back face of said free end, and when said free end is engaged in a slot in said unitary body, and the adhesive area exposed and folded back and then adhered to said unitary body.

3. A device with an elongated severable element with two free ends with an adhesive area on the back face of the two free ends. A seal being made when the two adhesive areas are mated together. Indicia fields and sterilization indicator fields can be applied along the elongated element.

The body of the tamper evident device of the present invention is preferably made from paper tag stock, paperboard or other suitable biodegradable material. The preferred material is 12 point (.012" caliper) paperboard tag stock. The caliper of tag stock was selected as being most compatible with available in-line printing and die-cutting equipment. Higher caliper material may be desirable in some applications but would most likely require an off-line secondary die-cutting operation. An acceptable caliper range for the paperboard tag stock being 12-24 point. The preferred material of heavy paper or paperboard may also consist of multiple layers of paper/paperboard laminated to achieve desired thickness and/or stiffness.

Other biodegradable materials that could be used to make the device of the present invention include wood, natural fabrics, composites of natural materials in a matrix of biodegradable and non-toxic binders, laminates of natural fabrics and wood.

A polymeric film could also be used but would deviate from the intended environmental solution to waste disposal and atmosphere pollution, unless one is found to be biodegradable and non-toxic.

The sterilization indicator ink in the preferred form and commercially available under trade designation G/S FWC-428C from Tempil Incorp, N.J. The composition may be flexographically printed at any appropriate location. The sterilization indicator ink being reactive to both steam or ethylene oxide gas sterilization processes with the ink changing a distinctive and different color under each sterilization condition. Without deviating from the intended purpose, one or more sterilization indicator ink formulations may be applied, each designed to react to a different sterilization process condition with a distinctive and different color change for each process condition.

The permanent type pressure sensitive adhesive in the form of a double-side adhesive laminate such as Adhesives Research, Inc., grade DEV 7427 CO 6504D or equivalent may be used. Pressure sensitive adhesive may be directly applied to the paperboard as a discrete adhesive element and a release liner applied as a secondary operation.

Although the invention is illustrated and described in relationship to specific embodiments, it is nevertheless not intended to be limited to the details shown, since various modifications and structural changes may be made without departing from the spirit of the invention.

WHAT IS CLAIMED IS:

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1. A locking device in the shape of a unitary body formed from a bio-degradable material which includes an element with at least one free end formed integral with said body, said element designed to engage and secure a container lock mechanism when the container is in a closed position, whereby the free end of the element is capable of being mechanically or adhesively secured to said unitary body to form a seal, with said device being designed to fracture upon opening of the container lock mechanism thereby providing visible evidence of the lock mechanism being opened.

2. A locking device in the shape of a unitary body which includes an element with at least one free end formed integral with said body, said element designed to engage and secure a container lock mechanism when the container is in a closed position, whereby the free end of the element is capable of being mechanically or adhesively secured to said unitary body to form a seal, with said device being designed to fracture upon opening of the container lock mechanism thereby providing visible evidence of the lock mechanism being opened.

3. A locking device in the shape of a unitary body formed from a bio-degradable material which includes a severable element with at least one free end formed integral with said body, said element designed to engage and secure a container lock mechanism when the container is in a closed position, whereby the free end of the element is capable of being mechanically or adhesively secured to said unitary body to form a seal, with said device being designed to fracture upon opening of the container lock mechanism thereby providing visible evidence of the lock mechanism being opened.

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4. A locking device which comprises a body portion having integral therewith a severable element which has a free end formed by appropriate die cuts which also results in the formation of an opening or hole which serves as a means for locating the device on the closure means of a lock mechanism, adhesive means also contained on said body positioned to enable contact with the free end of said severable element to seal or lock said device.

5. The device of claim 4 which further contains a sterilization indicator means on the body of said device.

6. A device of claim 4 which includes indicia means on the body of said device for providing information relative to the use of the device and the sterilization process.

7. A tamper evident locking device suitable for use in locking a sterilization container which comprises a body formed of heavy paper or paperboard tag stock, a severable element integral with said body and having a free end adapted for locking the device, locking means integral with said device and designed for engagement with said free end to lock said device.

8. The device of claim 7 which further includes sterilization indicator means on the body of said device.

9. The device of claim 7 which further includes indicia means for providing information relative to the use of the device and sterilization process.

10. A locking device which is made of a a bio-degradable material, said device comprising a body portion, containing integral therewith a severable element having a adapted free end for securing a sterilization container latch mechanism after said container has been closed and sealed, said severable element

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adapted to be secured at its free end by adhesive means contained on the body portion of said device to complete said lock or seal of said device with said severable element being fractured upon opening of said sterilization container.

11. The device of claim 8 which further includes on the body of the device, indicia fields for monitoring the sterilization process and use of the device, and the sterilization indicator means contained on the body of said device.

12. A method for securing a lock mechanism of a sterilization container to provide evidence of the mechanism being opened which comprises;

(a) providing a locking device in the shape of a unitary body formed from a bio-degradable material which includes an element with at least one free end formed integral with said body, said element designed to engage and secure the container lock mechanism when the container is in the closed position, whereby the free end of the element is capable of being mechanically or adhesively secured to said unitary body to form a seal, with said device being designed to fracture upon opening of the container lock mechanism; and

(b) securing the lock mechanism of the container by mechanically or adhesively securing said element to said unitary body to form a seal which upon opening of the container lock mechanism provides visible evidence of the lock mechanism having been opened.



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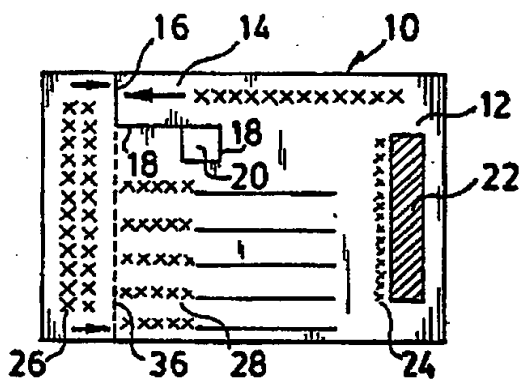


FIG. 1

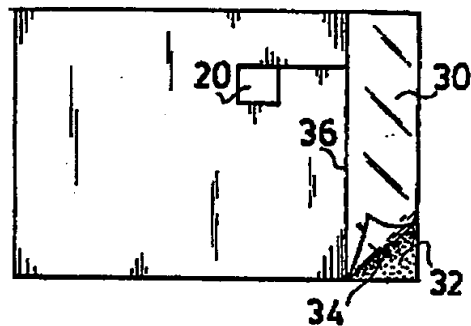


FIG. 2

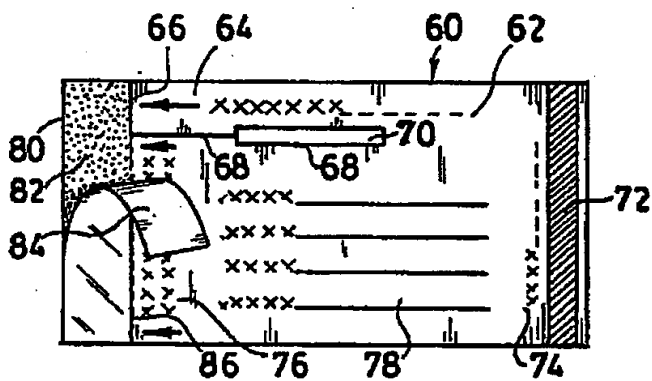


FIG. 5



FIG. 3

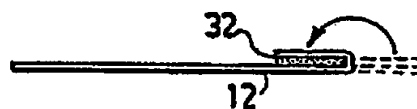


FIG. 4

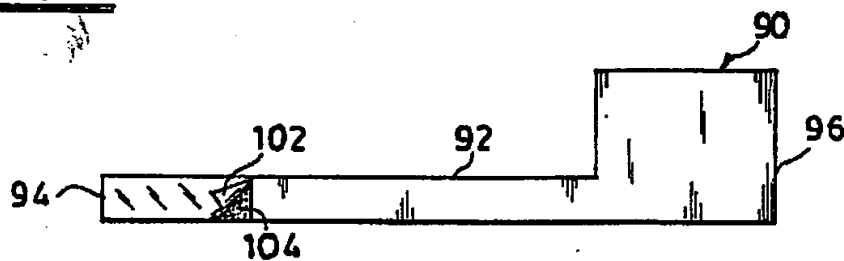


FIG. 6A

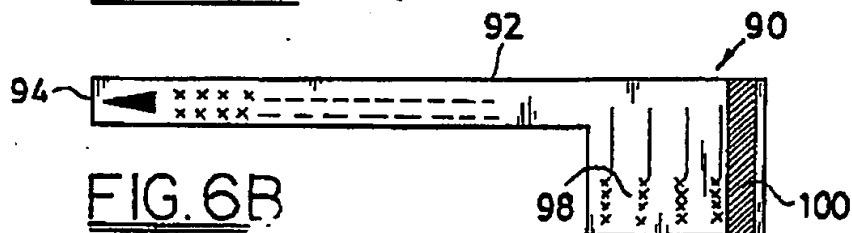


FIG. 6B

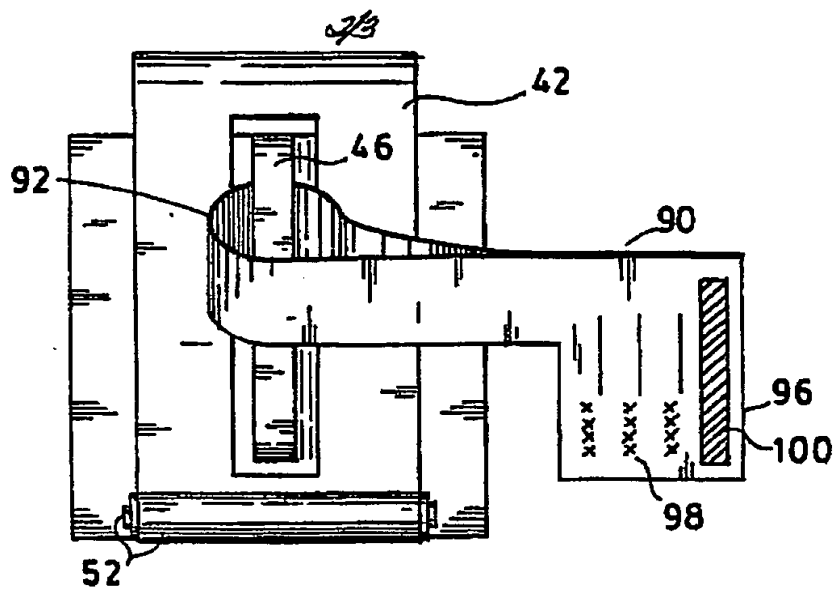


FIG. 6C

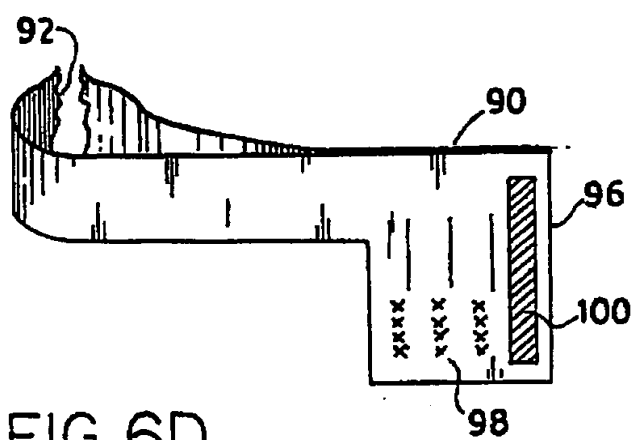


FIG. 6D

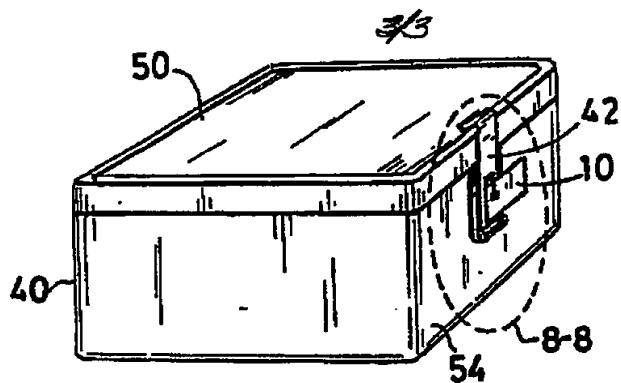


FIG. 7

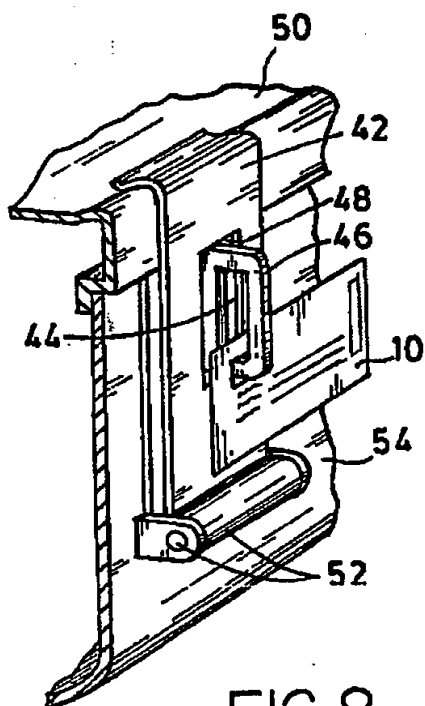


FIG. 8

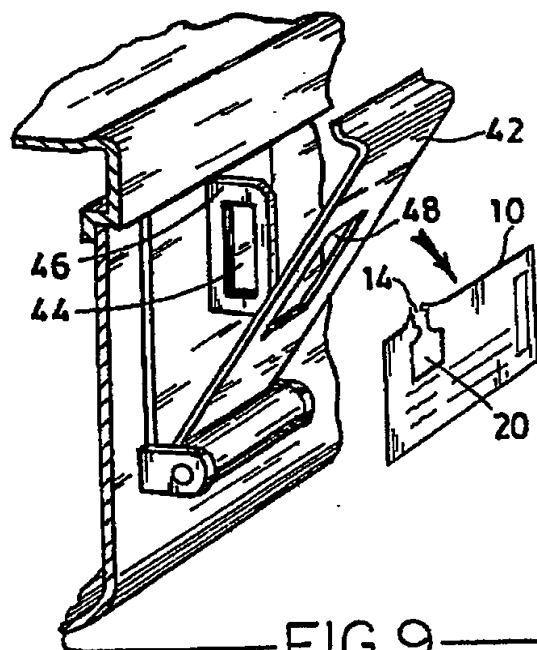


FIG. 9

# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/07249

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC(5): B65D 27/30; B65D 55/06; A61L 2/06; G01N 31/22 U.S.C1: 422/26,56,119,300,310;436/1;220/214;292/307A		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
U.S.C1.	422/56,26,119,300,310; 436/1; 220/214; 292/307A	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched <sup>8</sup>		
APS: INVENTOR SEARCH		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b>		
Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
Y	US,A, 4,562,047, (Sestak et al.) 31 December 1985. See figures 18-29 and associated discussion.	1-12
Y	US,A, 3,034,819, (Tupper) 15 May 1962. See entire document.	1-12
Y	US,A, 4,820,499, (Tasehner) 11 April 1989. See entire document.	1-12
Y	US,A, 1,602,309, (Martineau) 05 October 1926. See entire document.	1-4,7, 10,12
Y	US,A, 3,924,800, (Desmond et al.) 09 December 1975. See Figure 2 and column 1 lines 53-61.	1-4,7, 10,12
<p>* Special categories of cited documents: <sup>14</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Z" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
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International Searching Authority	Signature of Authorized Officer	
RO/US	Arlen Soderquist	
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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
Y	US,A, 858,264, (Daugherty) 25 June 1907. See entire document.	1-4,7,10, 12
Y	US,A, 1,799,701, (Prudden) 07 April 1931. See figures 2 and 3.	1-4,7,10, 12
A	US,A, 3,078,182 (Crone, Jr. et al) 19 February 1963.	5,6,8,9, 11
A	US,A, 4,194,622, (Lewis) 25 March 1980.	5,6,8,9, 11
A	US,A 4,783,321 (Spence) 08 November 1988.	1-12
A	US,A 4,331,257, (Tascher) 25 May 1982.	1-12
A	US,A, 4,818,502, (Tascher) 04 April 1989.	1-12
A	US,A, 4,915,913, (Williams et al.) 10 April 1990.	1-12
A	US,A, 4,363,421, (Shoemaker) 14 December 1982.	1-12
A	US,A, 4,454,956, (Patterson) 19 June 1984.	1-12
A	US,A, 4,625,885, (Nichols) 02 December 1986.	1-12
A	US,A, 4,709,396, (Voshall et al.) 24 November 1987.	1-12
A	US,A, 4,749,084, (Pereyra) 07 June 1988.	1-12



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